

### **REASONS FOR ALLOWANCE**

An examiner's statement of reasons for allowance follows. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2009 has been entered.

The claims have been amended to further limit the claimed invention to a vaccine comprising a recombinant canarypox vector expressing WNV polyprotein prM-M-E. Previously, claims were rejected as prima facie obvious over the combined teachings of Paoletti 5744141 (teaching recombinant poxvirus immunogens expressing flavivirus polyprotein), Chang US 20030022849 (teaching a DNA vaccine effective to prevent WNV viremia after mosquito bites), and Paoletti 5505941 (teaching recombinant avipox vaccine vectors, including canarypox).

Applicants have provided several lines of evidence relevant to secondary considerations of nonobviousness. Evidence of commercial success for the canarypox

PrM-M-E vaccine is presented in the declaration by Bob Nordgren. According to the declaration, this vaccine was the second veterinary vaccine marketed against WNV, and showed a steady market share (6-11%) over the first five years after introduction.

In addition, the publication by Siger et al (Veterinary Therapy 7:249-256, 2006; exhibit E) provides evidence that the claimed vaccine is effective at preventing disease under very demanding challenge conditions. Unlike the challenge test performed by Chang, the intrathecal challenge in Sigur 2006 was sufficient to cause neurological symptoms in 8/10 unvaccinated horses. Only 1/10 horses vaccinated with the claimed vaccine showed even mild neurological symptoms. One of ordinary skill in the art could not have predicted whether or not the canarypox-vectored vaccine would succeed in this challenge, based upon the results of the lesser challenge in Chang.

Therefore, considering the teachings of the prior art together with the secondary considerations of commercial success and the unpredictable (and therefore unexpected) success in very stringent challenge conditions, and considering the nexus between the invention as now claimed and the secondary considerations, the rejection of the claims as obvious is withdrawn.

In addition, the provisional double patenting rejection over 10679520 is withdrawn, because that application has been abandoned.

### ***Priority***

Upon reviewing the records in this case, it was determined that applicant cannot claim benefit under 35 USC 120 as a CIP of international application PCT/FR02/01200, because the international application did not designate the United States. Also, benefit

under 35 USC 119 to FR 01/04737 is denied; no U.S. application claiming benefit was filed within a year of the French filing date, therefore the conditions of 119(a) were not met.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ruoying Chen on 1/12/2010.

In the specification, page 1, line 12, "a continuation-in-part of" has been changed to --related to--.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is (571)272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/  
Primary Examiner, Art Unit 1648

1/11/10